

**PACKAGE LEAFLET: INFORMATION FOR THE PATIENT**  
**HISTEK 10MG FILM-COATED TABLETS**  
**(CETIRIZINE DIHYDROCHLORIDE)**

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet:**

1. What Histek is and what it is used for
2. What you need to know before you take Histek
3. How to take Histek
4. Possible side effects
5. How to store Histek
6. Contents of the pack and other Information

**1. What Histek is and what it is used for**

**The name of your medicine is Histek 10mg Film-coated Tablets**

The active substance of Histek 10mg Film-coated tablets is cetirizine. Cetirizine belongs to a group of medicines called antihistamines. It is used to treat the symptoms of hay fever (itchy, runny and blocked-up nose; sneezing; watery eyes) and other allergic reactions, including those affecting the skin in adults and children aged 6 years and over.

Ask your doctor if you have any questions about why you have been given this medicine.

**2. What you need to know before you take Histek**

To make sure that it is safe for you to take Histek, please read the following section carefully.

**Do not take Histek if:**

- you are hypersensitive (allergic) to cetirizine dihydrochloride, hydroxyzine or any other medicine in the piperazine class. An allergic reaction may include rash, itching, or shortness of breath.
- you are allergic to any of the other ingredients of Histek listed in section 6.
- you have severe kidney failure (creatinine clearance less than 10ml/min)

If any of the above applies to you talk to your doctor or pharmacist before taking the Histek.

**Warnings and precautions**

Talk to your doctor or pharmacist before taking Histek if you:

- have any kidney or liver problems, or are on haemodialysis – please consult your doctor for advice
- have problems with the ability to completely empty the bladder (urinary retention)
- have epilepsy or are at risk of epilepsy (recurring seizures or fits)

**Other medicines and Histek**

Please inform your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, even those not prescribed. Concurrent use of cetirizine with other CNS depressants should also be avoided as reduction in alertness and impairment of performance may occur. Histek is known to interact with a medicine used for asthma called theophylline.

#### **Histek with food, drink and alcohol**

In common with other antihistamines it is recommended that alcohol consumption be avoided. Alcohol may make you feel drowsy and should be avoided while you are taking Histek.

#### **Pregnancy, Breast feeding and Fertility**

If you are pregnant or breast feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. Histek has been shown to pass into breast milk and therefore breast-feeding mothers should speak to a doctor or pharmacist before using this medicine.

#### **Allergy skin tests**

If you are due to have allergy skin tests, ask your doctor if you should stop taking Histek. Your doctor may recommend stopping Histek 3 days before testing is performed as Histek may affect the allergy skin test results.

#### **Driving and using machines**

A few people have experienced dizziness, drowsiness or fatigue after taking Histek . If affected, do not attempt any skilled tasks such as driving or operating machinery. Do not exceed the recommended dose.

#### **Histek contains lactose**

This product contains lactose, if you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

### **3. How to take Histek**

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is:

**Children aged from 6 to 12 years:** Half a tablet (5 mg) twice daily

The tablets need to be swallowed with a glass of water, milk or fruit juice.

**Adults, elderly and children over 12 years of age:**

One tablet (10mg) once a day

Patients with liver problems: No dose adjustment is needed in patients with liver problems alone.

Patients with liver problems and kidney problems: Dosage should be adjusted by your doctor.

Patients with kidney problems: Dosage should be adjusted by your doctor.

**If you have any further questions on the use of this medicine, ask your doctor or pharmacist.**

Histek 10mg Film-Coated Tablets are not recommended for children under 6 years of age as the formulation is not suitable for this age group.

If you have the impression that the effect of Histek is too strong or too weak, talk to your doctor or pharmacist.

**If you take more Histek than you should:**

Never take more tablets than your doctor advises you as this may harm you.

If you or someone else have accidentally taken more tablets than you should, talk to your doctor or pharmacist immediately or go to your nearest hospital casualty department. Take this leaflet with you if you still have it. Histek may make you feel drowsy or dizzy if you take too many - so do not drive.

**If you forget to take Histek:**

If you miss a dose, take one as soon as you remember, then go on as before but always leave at least 12 hours between doses. Do not take a double dose to make up for missed doses.

If you have any further questions on the use of this medicine ask your doctor or pharmacist.

#### **4. POSSIBLE SIDE EFFECTS**

Like all medicine, this medicine can cause side effects, although not everybody gets them.

**The following side effect is very rare, however, stop taking the medication straight away and seek urgent medical advice if:**

You experience a severe allergic reaction including rash, itchiness and fever, swollen throat, face, eyelids or lips. This reaction may start soon after you first take the medicine, or it might start later.

**The following side effects have also been reported.**

**Common side effects** (affects less than 1 in 10 people)

Sleepiness (somnolence), tiredness (fatigue)

Dizziness

Headache

Dry mouth

Feeling sick (nausea)

Abdominal pain

Cold-like symptoms of the nose, e.g. sneezing/runny nose (children only)

Sore throat

Diarrhoea (children only)

**Uncommon side effects** (affects less than 1 in 100 people)

Diarrhoea  
Weakness (Asthenia)  
Feeling unwell (Malaise)  
Unusual touch sensation, tingling (Paraesthesia)  
Agitation  
Itchy skin or skin rash (Pruritus)  
Rash

**Rare side effects** (affects less than 1 in 1000 people)

Rapid heartbeat (Tachycardia)  
Swelling (Oedema)  
Hepatic (liver) - abnormal function,  
Weight increase  
Convulsions  
Aggression  
Confusion  
Depression  
Sleeping difficulties (Insomnia)  
Hives (Urticaria)  
Hallucinations

**Very rare side effects** (affects less than 1 in 10,000 people)

Presence of relatively few platelets in blood (Thrombocytopenia)  
Inability to change focus (Eye accommodation disorder) Blurred vision, circular motion of the eyeball in any direction (oculogyration)  
Unusual taste (Dysgeusia)  
Partial or complete loss of consciousness with interruption of awareness of oneself and ones surroundings (Syncope)  
Welts under the skin (angioneurotic oedema)  
Tremor and abnormal movements  
Urinary problems – including increase in need to urinate (micturition difficulty), pain or difficulty in passing urine (Dysuria), passing of urine without control (Enuresis).  
Tics

**Not known side effects**

Vertigo  
Loss of memory or memory impairment  
Suicidal thoughts  
Increase in appetite  
Urinary retention

In some cases **high levels of liver enzymes** and **bilirubin** (breakdown of haemoglobin from red blood cells) have been reported, however these effects usually wear off as soon as you stop taking Histek.

Side effects can be minimised by taking half dose twice daily (i.e. half tablet in the morning and the other half in the evening).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

### **Reporting of side effects**

If you get any side effects, talk to your doctor or Pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects via Health Products Regulatory Authority, Kevin O'Malley House, Earlsfort Centre, Earlsfort Terrace, Dublin 2, and Ireland. Tel: +353 1 6764971, Fax: +353 1 6762517, Website: [www.hpra.ie](http://www.hpra.ie), e-mail: [hprapharmacovigilance@hpra.ie](mailto:hprapharmacovigilance@hpra.ie).

### **5. How to store Histek**

Keep out of the sight and reach of children.  
There are no special storage precautions.

Do not use after the expiry date or "Use before" date stated on the carton or blister.  
The expiry date or "Use before" refers to the last day of that month.

It is recommended that you take any leftover medicines back to your pharmacist for safe disposal after you have stopped taking them. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help protect the environment.

### **6. CONTENTS OF THE PACK AND OTHER INFORMATION**

#### **What HISTEK 10mg FILM-COATED TABLETS contains:**

The active substance of Histek 10mg FILM-COATED TABLETS is: 10mg of cetirizine hydrochloride.  
The other ingredients are tablet core: cellulose, microcrystalline, lactose monohydrate, crospovidone, silica, colloidal anhydrous, magnesium stearate, film-coating: hypromellose, macrogol stearate, cellulose, microcrystalline, propylene glycol and titanium dioxide, E171

#### **What HISTEK 10mg FILM-COATED TABLETS looks like and contents of the pack:**

Film-coated, white or almost white convex, oval shaped, tablets. Scored on one side.  
The tablets are marked "C" on one side, "J" and "E" on either side of the central division line on the reverse.  
The tablets can be divided into equal halves.  
Histek 10mg Film-coated tablets are available in blister pack of 30 tablets.

#### **Product Authorisation holder:**

Fannin Limited, Fannin House, South County Business Park

#### **Manufacturer:**

Actavis hf, Reykjavikurvegur 78, IS-220 Hafnarfjörður, Iceland.

Actavis UK Ltd., Whiddon Valley, Barnstaple, Devon EX32 8NS, England.

Product Authorisation number:  
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